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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,724

12/06/2005

Yoshiaki Suzuki

P26894

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7055 7590 07/02/2009  
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EXAMINER

ZACHARIA, RAMSEY E

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

07/02/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/525,724	SUZUKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ramsey Zacharia	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-14 and 16-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/22/09;06/02/09</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2009 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

3. Claims 7, 9, 11-14, 16, 20, 22, 24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Murayama et al. (US 5,891,192).

Murayama et al. teach an intraluminal implant (i.e. artificial blood vessel) comprising a protein coating and subjected to ion implantation (column 1, lines 57-67). The implant body may comprise silicone (column 2, lines 52-53). The proteins are cell adhesion proteins such as fibronectin and fibrinogen (column 2, line 64-column 3, line 8). Suitable ions include He<sup>+</sup>, C<sup>+</sup>, N<sup>+</sup>, Ne<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, N<sub>2</sub><sup>+</sup>, O<sub>2</sub><sup>+</sup>, Kr<sup>+</sup>, H<sup>+</sup>, and Ar<sup>+</sup> (column 3, lines 10-12). The fluency of ions implanted is in the range of about 10<sup>14</sup>-10<sup>18</sup> ions/cm<sup>2</sup> (column 3, lines 13-15).

Art Unit: 1794

Regarding claim 11, the mere designation of the silicone as an artificial dura mater represents an intended use and does not contribute a substantive process limitation to the method of claim 7.

***Claim Rejections - 35 USC § 103***

4. Claims 7-14, 17, 19, 21, 23, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore et al. (US 6,503,527) in view of Suzuki et al. (Ionics, vol. 25, no. 1, pp 47-54).

Note: for the above Suzuki reference, this action refers to page and line number of the attached English language translation.

Whitmore et al. is directed to a fibrin glue composition (column 2, lines 23-34). The composition may be used as an adhesive in neurosurgery to anchor dural patches (column 3, lines 1-14).

Whitmore et al. is silent as to the composition of the dural patch.

Suzuki et al. teach an artificial dura material comprising ePTFE subjected to ion beam irradiation to impart cellular attachability (page 5, lines 9-20). The ePTFE is irradiated with  $\text{Ne}^+$  ions at a fluence of  $10^{15}$  ions/cm<sup>2</sup> for the most improved degree of attachability (page 10, lines 9-13).

One skilled in the art would be motivated to use the artificial dura material of Suzuki et al. as the dural patch of Whitmore et al. because it exhibits improved cell attachability and thus would be expected to result in a stronger bond with the fibrin glue composition.

Art Unit: 1794

Moreover, it would have been obvious for one skilled in the art to use the treated ePTFE of Suzuki et al. as the dural patch of Whitmore et al. since it has been held that the selection of a known material (e.g. ion treated ePTFE) based on its suitability for its intended use (e.g. artificial dura mater) supported a *prima facie* obviousness determination. See MPEP 2144.07.

Regarding claim 8, it would have been obvious to only irradiate the portion of the dural patch on which the fibrin glue is to be applied since it is only where the fibrin glue is to be applied that improved attachability to the fibrin glue would be required.

5. Claims 16, 18, 20, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore et al. (US 6,503,527) in view of Suzuki et al. (Ionics, vol. 25, no. 1, pp 47-54) as applied to claims 7-9 and 11-14 above, and further in view of Klein et al. (US 2004/0005364).

Whitmore et al. taken in view of Suzuki et al. teach all the limitations of claims 16, 18, 20, 22, 24, and 26, as outlined above, except for the use of silicone as the artificial dura mater material. Suzuki et al. do teach the use of polypropylene and expanded polytetrafluoroethylene as suitable for use as the artificial dura mater material (page 6, lines 1-2).

Klein et al. is directed to a mesh material that may be used for treating or repairing tissue at a surgical site (paragraph 0068). The mesh material may be a synthetic materials such as polypropylene, expanded polytetrafluoroethylene, and silicone (paragraph 0071).

Klein et al. show that polypropylene, expanded polytetrafluoroethylene, and silicone are known in the art as functionally equivalent materials for use as materials for treating or repairing tissue at a surgical site comparable to dura mater. Therefore, because these polymers were art-

Art Unit: 1794

recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute silicone for the expanded polytetrafluoroethylene or polypropylene of Suzuki et al.

Moreover, it would have been obvious for one skilled in the art to use silicone since it has been held that the selection of a known material (e.g. silicone) based on its suitability for its intended use (e.g. material for treating or repairing tissue) supported a *prima facie* obviousness determination. See MPEP 2144.07.

### ***Response to Arguments***

6. Applicant's arguments filed 22 April 2009 with respect to the rejection over Whitmore et al. in view of Suzuki et al. have been fully considered but they are not persuasive.

The applicants argue that from the results of the *in vitro* experiment of Suzuki, one skilled in the art would not have been capable of predicting that fibrinogen (a component of fibrin glue) is adsorbed to a polymer irradiated with an ion beam.

This is not persuasive for at least the reason that, even if the skilled artisan could not predict the effect of irradiation the polymer on fibrinogen adsorption, one skilled in the art would still be motivated to use the treated ePTFE of Suzuki et al. as the dural patch of Whitmore et al. since it has been held that the selection of a known material (e.g. ion treated ePTFE) based on its suitability for its intended use (e.g. artificial dura mater) supported a *prima facie* obviousness determination.

The applicants further argue that their originally filed application includes Examples which reveal that the adhesiveness between fibrin glue and ePTFE was remarkably improved in

Art Unit: 1794

the case of ion beam-irradiated ePTFE as compared to untreated ePTFE. The applicants also submitted the Kobayashi et al. reference revealing an unexpected adhesiveness when comparing ion beam-irradiated silicone with untreated silicone.

The results presented in the specification are not persuasive for at least the reason that the claims as written do not appear to be commensurate in scope with the showing. The specification illustrates one example using ePTFE irradiated with  $\text{Ne}^+$  ions at  $5 \times 10^{14}$  ions/cm<sup>2</sup> while claim 7 permits any ions at irradiated at any dose. The dose of irradiation appears to be a significant variable (see page 7, lines 13-18 of the instant specification as well as page 10, lines 9-15 of the Suzuki et al. reference); by not restricting the dose of irradiation the scope of the claims as written are broader than the evidence offered to support the contention of non-obviousness. Additionally, since Suzuki et al. show that irradiation alters the ePTFE such that cell attachment appears while no cell attachment is seen with untreated ePTFE, one skilled in the art would expect a degree of enhanced attachability to extend to biological adhesives as well.

The purported showing of the Kobayashi et al. reference is insufficient for at least the reason that the data therein is not presented in declaration or affidavit form. It has been held that evidence is required in declaration or affidavit form to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001. Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. See MPEP 716.02(g).

Art Unit: 1794

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday and Thursdays from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho, can be reached at (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ramsey Zacharia/

Primary Examiner, Art Unit 1794